APR 1 7 2002

K020890

510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, Daig Division, Inc.
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 352-9737
Contact Person:	Kirk S. Honour
Date Submission Prepared:	March 18, 2002

B. Device Information

Common or Usual Name:	Spyglass™ Angiographic Catheter
Classification Name:	Angiographic Catheter
Predicate Device:	Spyglass™ Angiographic Catheter
Device Description:	The Spyglass™ Angiographic Catheter is a fixed-curve, catheter that are allows introduction of contrast media to the body.
Intended Use:	Spyglass™ Angiographic catheters are designed for the delivery of radiopaque contrast media during angiographic procedures.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Spyglass™ Angiographic Catheters are substantially equivalent to the predicate device including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division considers the Spyglass™ 4Fr Angiographic Catheters to be substantially equivalent to the predicate device, Spyglass™ 6Fr & 5Fr Angiographic Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Mr. Kirk S. Honour
Regulatory Affairs
St. Jude Medical
DAIG Division
14901 Deveau Place
Minnetonka, MN 55345-2126

Re: K020890
Trade Name: Spyglass™ Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Angiographic Catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: March 18, 2002
Received: March 19, 2002

Dear Mr. Honour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Divison of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020890

Device Name: Spyglass™ Angiographic Catheter

Indications for Use:

Spyglass™ Angiographic Catheters are designed for delivery of radiopaque contrast media during angoigraphic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020890

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)